

Root-cause analysis for clot in blood bag

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Clots present in the packed red cell unit can go unnoticed and lead to flow problems during transfusion. We observed a long thread-like clot in a blood bag during component preparation and therefore performed a root-cause analysis of the event [Figures 1 and 2].

Root-cause analysis is a methodology that reveals all the influencing and causal factors that have led to an adverse or near-miss event. It is done by a multi-professional team, in this case our team consisted of a medical officer, a resident, a technician, and the staff nurse posted in the donor complex. We started gathering information from the donor area, and then mapped the information to identify the problem and the contributing factors. Once all the team members agreed on the cause identified, we made a final report and took a corrective action. The recommendations for prevention of recurrence of such event were proposed.

In the present case, the blood collection monitor (Terumo Penpol, India) started giving low flow alarm within a minute of phlebotomy in a healthy donor. Phlebotomy site was inspected for any signs of hematoma or extravasation of blood and position of the needle was manipulated to achieve better flow. The donor was asked to press the rubber ball to increase the venous return and the cuff pressure in the blood pressure (BP) apparatus tied was raised by 10 mmHg. As the alarm persisted and the flow rate did not improve, the needle was removed in 4 min. A total of 88 mL of blood was collected in a 350-mL double bag. The collection monitors generally analyze the flow of the blood through the tubing at every 30 s during the collection phase. As per the instruction manual of the blood collection monitor, the flow rate during the collection phase can be categorized under three grades as follows: low flow, optimal flow, and high flow rates.^[1] "Low flow" indicates a flow rate less than 10 mL every 30 s, while "high flow" is more than 90 mL every 30 s, and it is considered optimal when the flow rate is between 10mL and 90 mL every 30 s. Hence, in this case, the flow rate must have been persistently lower than the threshold for the "low flow.". In addition to the low flow rate, the fact that the first 90-cm tube attached to the bag is not coated with any anticoagulant also might have

contributed to the activation of coagulation. The clot had formed throughout the length of the tube resulting in the thread like appearance and finally at the end of the collection it slipped into the bag [Figure 1]. Following the root-cause analysis, we have instructed the technical staff to check the flow rate in the collection monitor in case of an alarm and stop the collection if it does not get corrected within 2 min.

Many a times even with a low flow alarm, we tend to continue and complete the collection to avoid wastage of the bag and the precious resource. As shown in the fish-bone diagram, various factors related to the personnel, machine, material, and the technique can influence the clot formation [Figure 2]. The rate and the extent of clot

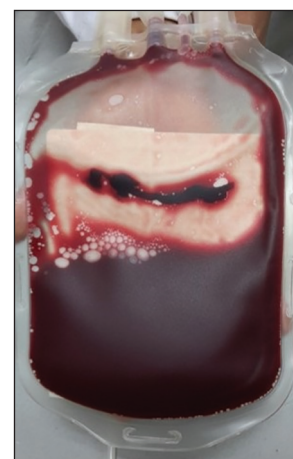


Figure 1: Clot in blood bag

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Cite this article as: Shastry S, Das S. Root-cause analysis for clot in blood bag. Asian J Transfus Sci 2016;10:3-4.

Access this article online

Website: www.ajts.org

DOI: 10.4103/0973-6247.175385

Quick Response Code:



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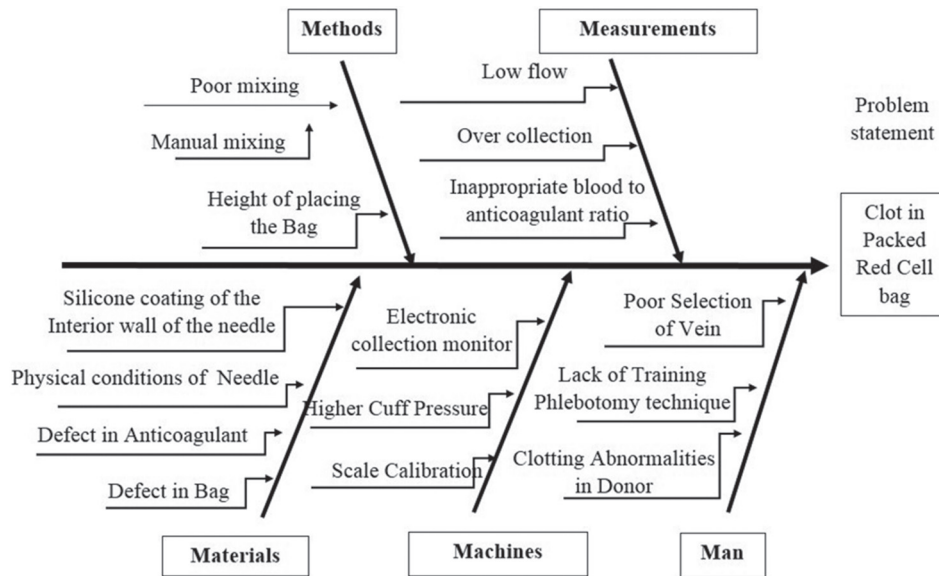


Figure 2: Fish-bone analysis of clot in blood bag

formation *in vitro* are also affected by the chemical composition of the substrate, physical circumstances, such as flow rate, space width, and surface energy.^[2] Blood flow rate regulates the thrombus formation, and under low flow conditions, fibrin formation is abundant and high flow rate increases shear rate and promotes initial attachment of the platelets.^[3] However, we could not find the exact value in the literature to define “low flow” rate that stimulates the clot formation *in vitro*. The newer generation of blood collection monitors safety feature, where automatic camp functions if the flow rate is less than 20 mL per min for more than 2 min. As per the American Association of Blood Banks (AABB) guidelines, it is advisable not to prepare platelet and plasma components, if the collection time exceeds by more than 10 min and 15 min, respectively. But no such guidelines exist for packed red cell bags.^[4] Further study to know the exact relation between the flow rate in the tubing of blood collection bag and the rate of clot formation *in vitro* will be useful.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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